

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

NATURAL RESOURCES DEFENSE)	
COUNCIL, INC.,)	
)	
Plaintiff,)	
)	
v.)	10 Civ. 5690 (AKH) (AJP)
)	
UNITED STATES FOOD AND DRUG)	
ADMINISTRATION; KATHLEEN SEBELIUS,)	
in her official capacity as Secretary, United States)	
Department of Health and Human Services; and)	
MARGARET HAMBURG, in her official capacity)	
as Commissioner, United States Food and Drug)	
Administration,)	
)	
Defendants.)	
)	

PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

Pursuant to Rule 56 of the Federal Rules of Civil Procedure, plaintiff Natural Resources Defense Council hereby moves for summary judgment on the basis that there is no genuine issue of material fact, and plaintiff is entitled to judgment as a matter of law. Defendants have violated the Administrative Procedure Act (“APA”), 5 U.S.C. § 555(b), and the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355, *amended by* Pub. L. 111-148, 124 Stat. 119, by failing to promulgate a final regulation for topical antimicrobial drug products containing triclosan and triclocarban, for over-the-counter human use. Under federal law, defendants must either establish the safety, effectiveness, and labeling accuracy of products containing these chemicals, or prohibit the marketing of the products. Defendants have done neither, despite mounting evidence that triclosan and triclocarban pose significant health risks and are not more effective than washing with regular soap and water. More than three decades have passed since

defendants first proposed regulation of products containing triclosan and triclocarban. This delay is unreasonable as a matter of law. *See APA*, 5 U.S.C. § 706(1).

In support of this motion, plaintiff submits the accompanying (1) memorandum in support of plaintiff's motion for summary judgment; (2) statement of material facts as to which there is no genuine dispute; (3) Declaration of Sarah Janssen, M.D., Ph.D., M.P.H., and attached exhibit; (4) declaration of Linda Lopez; (5) Declaration of Diana Owens; (6) Declaration of Megan Schwarzman, M.D., M.P.H.; (7) Declaration of Vivian H.W. Wang, and attached exhibits; and (8) proposed order.

Respectfully submitted,

/s/ Vivian H.W. Wang
Mitchell S. Bernard (MB 5823)
Nancy S. Marks (NM 3348)
Vivian H.W. Wang (VW 2604)
Natural Resources Defense Council
40 West 20th Street
New York, New York 10011
(212) 727-2700

Counsel for Plaintiff

Dated: September 24, 2010

TABLE OF DECLARATIONS AND EXHIBITS

DECLARATIONS

Sarah Janssen, M.D., Ph.D., M.P.H.
Linda Lopez
Diana Owens
Megan Schwarzman, M.D., M.P.H.
Vivian H.W. Wang

EXHIBITS

- 1) Curriculum Vitae, Sarah Janssen, M.D., Ph.D., M.P.H.
- 2) FDA, Over-the-Counter Antibacterial Ingredients in Drug Products for Repeated Daily Human Use, 37 Fed. Reg. 235 (Jan. 7, 1972)
- 3) FDA, Proposal to Establish a Monograph for OTC Topical Antimicrobial Products, 39 Fed. Reg. 33103 (Sept. 13, 1974)
- 4) FDA, OTC Topical Antimicrobial Products: Tentative Final Order, 43 Fed. Reg. 1210 (Jan. 6, 1978)
- 5) FDA, Tentative Final Monograph for Health-Care Antiseptic Drug Products, 59 Fed. Reg. 31402 (June 17, 1994)
- 6) FDA, Health-Care Antiseptic Drug Products: Reopening of the Administrative Record, 68 Fed. Reg. 32003 (May 29, 2003)
- 7) FDA, Consumer Updates, "Triclosan: What Consumers Should Know" (April 8, 2010)
- 8) Letter from Sarah Janssen, Staff Scientist, NRDC, to Dr. Jesse Goodman, Chief Medical Officer, FDA (Sept. 30, 2009)
- 9) Letter from Jesse L. Goodman, Chief Scientist, FDA, to Jennifer Sass, Senior Scientist, NRDC (May 28, 2010)
- 10) Letter from Edward J. Markey, Chairman, House Subcommittee on Energy and Environment, to Margaret Hamburg, Commissioner, FDA (Jan. 5, 2010)
- 11) Letter from Jeanne Ireland, Assistant Commissioner for Legislation, FDA, to Edward J. Markey, Chairman, House Subcommittee on Energy and Environment (Feb. 23, 2010)

CERTIFICATE OF SERVICE

I certify that on September 24, 2010, I caused a copy of the foregoing Plaintiff's Motion for Summary Judgment and all associated documents cited therein to be filed using the Court's ECF system, which will serve the documents electronically on all counsel of record.

/s/ Vivian H.W. Wang
Vivian H.W. Wang
Counsel for Plaintiff